PTO-1390 (Rev. 02-2005)
Approved for use through 3/31/2007. OMB 0651-0021
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371

ATTORNEY'S DOCKET NUMBER	
1396-1-012PCT/US	
U.S. APPLICATION NO. (If known, see 37 CFR 1.5)	10/550965

INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/GB2004/001311	MARCH 26, 2004	MARCH 26, 2003

TITLE OF INVENTION
DRUG DELIVERY DEVICE COMPRISING A MESH SLEEVE

APPLICANT(S) FOR DO/EO/US
PETER KNOX

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☑ This is a **FIRST** submission of items concerning a submission under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a submission under 35 U.S.C. 371.
3. ☑ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.
4. ☑ The US has been elected (Article 31).
5. ☑ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
   a. ☑ is attached hereto (required only if not communicated by the International Bureau).
   b. ☑ has been communicated by the International Bureau.
   c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
   a. ☐ is attached hereto.
   b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☑ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
   a. ☑ are attached hereto (required only if not communicated by the International Bureau).
   b. ☑ have been communicated by the International Bureau.
   c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
   d. ☐ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☑ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). UNEXECUTED
10. ☐ An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11 to 20 below concern document(s) or information included:

11. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☑ A preliminary amendment.
14. ☐ An Application Data Sheet under 37 CFR 1.76.
15. ☐ A substitute specification.
16. ☐ A power of attorney and/or change of address letter.
17. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13*ter*.2 and 37 CFR 1.821- 1.825.
18. ☐ A second copy of the published International Application under 35 U.S.C. 154(d)(4).
19. ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
20. ☑ Other items or information: DRAWINGS - 1 SHEET - FIGS. 1A-F; COPY ISR; COPY WRITTEN OPINION;COPY REPLY WRITTEN OPINION; COPY NOTICE TRANSMIT INTL PRELIM REPT ON PATENTABILITY W/CLAIM AMEND; COPY PCT REQ; COPY PCT NOTICE RULE 47.1; PCT FORM 401; PCT FORM 402.

EXPRESS MAIL NO.: EV 652397822 US DATE OF DEPOSIT: SEPTEMBER 26, 2005

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U.S. APPLICATION NO. (if known, see 37 CFR 1.5)	INTERNATIONAL APPLICATION NO.	ATTORNEY'S DOCKET NUMBER
10/550965	PCT/GB2004/001311	1396-1-012PCT/US

The following fees have been submitted	CALCULATIONS	PTO USE ONLY
21. ☑ Basic national fee..... $300	$ 300.00	
22. ☑ Examination fee If International preliminary examination report prepared by USPTO and all claims satisfy provisions of PCT Article 33(1)-(4)..... $100 All other situations..... $200	$ 200.00	
23. ☑ Search fee Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority..... $100 International Search Report prepared and provided to the Office..... $400 All other situations..... $500	$ 500.00	
TOTAL OF 21, 22 and 23 =	$ 1,000.00	
☐ Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is **$250** for each additional 50 sheets of paper or fraction thereof.		

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole number)	RATE	
24 - 100 =	0 /50 =	0	x $250	$ N/A

Surcharge of **$130.00** for furnishing the oath or declaration later than 30 months from the earliest claimed priority date (37 CFR 1.492(h)).				$	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	$	
Total claims	34 - 20 =	14	x $ 50	$ 700.00	
Independent claims	1 - 3 =	0	x $200	$ 0	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)		YES	+ $360	$ 360.00	
			TOTAL OF ABOVE CALCULATIONS =	$ 2,060.00	
☑ Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by ½.					
			SUBTOTAL =	$ 1,030.00	
Processing fee of **$130.00** for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)). +				$	
			TOTAL NATIONAL FEE =	$ 1,030.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). **$40.00** per property +				$	
			TOTAL FEES ENCLOSED =	$ 1,030.00	
			Amount to be refunded:	$	
			Amount to be charged:	$	

a. ☑ A check in the amount of $ 1,030.00 to cover the above fees is enclosed.

b. ☐ Please charge my Deposit Account No. 11-1153 in the amount of $ _____ to cover the above fees. A duplicate copy of this sheet is enclosed.

c. ☑ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 11-1153. A duplicate copy of this sheet is enclosed.

d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. **Credit card information should not be included on this form.** Provide credit card information and authorization on PTO-2038.

NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.

SEND ALL CORRESPONDENCE TO:

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Attn: S.G. von Eggelkraut-Gottanka

YOUR REF

OUR REF P033619WO:HRG/SKT

7th July 2005

Dear Sirs,

Re: International patent application No. PCT/GB2004/001311
METRIS THERAPEUTICS LTD.

I refer to my telephone conversation of 15th June 2005 with the Examiner responsible for examination of this application, in which we discussed the relevance of D1 and D2 to this application.

Amendments

An amended page 20 is enclosed on which claim 1 has been amended to specify that the sleeve is "prepared separately from said device". Basis for this amendment is found at page 4, lines 9-10. The term "envelopes" in claim 1 has been corrected to state "envelops".

In making these amendments, any subject-matter that may have been deleted has not been abandoned in any way and may be reinstated or serve as the basis for one or more divisional or continuation applications in the respective national or regional phases.

Novelty and inventive step

The present invention relates to a mesh sleeve, which is prepared separately from a device, and into which a device can be inserted. Such a sleeve is neither disclosed nor suggested by D1.

FACSIMILE MESSAGE

To: **EPO Hague**
Fax No.: **00 31 70 340 3016**

This fax consists of 4 sheets. If a sheet is missing or has been imperfectly received, please contact us immediately (Tel: 020-7242 8692; Fax: 020-7405 4166). If you are not the addressee, please contact us immediately and then destroy this fax.

D1 discloses a fluid-impermeable lattice which is attached to the tampon and thus forms part of the device.

As explained in the description of D1 at page 14, Figures 13 and 14 show a side view of the lattice attached to the surface of a device. They do not show a separate mesh sleeve and neither is such a sleeve suggested by the disclosure of this document. All of the arrangements for fluid-impermeable layers that are set out in D1 describe instances where the fluid-impermeable layer forms an integral part of the device.

Methods for attaching the fluid-impermeable layer to the body of the device are described at page 5, lines 22-29. None of the methods discloses making a mesh sleeve which can envelop an existing device and which is prepared separately from the device.

As D1 in no way discloses or suggests the mesh sleeve of the present invention, claim 1 is novel and inventive over D1.

The mesh sleeve of claim 1 is also novel and inventive over D2. D2 discloses a medicated catamenial tampon comprising a foam corpus and a medicament-bearing non-woven overwrap. The overwrap of D2 forms an integral part of the catamenial tampon.

During manufacture of the overwrap of D2, there is a transient moment when a tube-like structure is formed from an essentially rectangular piece of material and one end of the tube is then closed (column 8, lines 8-13). The foam corpus is then placed within the overwrap and the other end is closed so that the overwrap wholly encases the foam corpus. The overwrap effectively forms a loose "sack" of material in which the foam corpus device sits. However, at the stage in which the overwrap forms a tubular structure, it is not a sleeve "adapted for use" with a device suitable for insertion into a bodily cavity as if any such device was inserted into the tubular structure, it would simply fall out again. Instead, in order for the overwrap to be suitable for use with a device, it is necessary to close both ends of the tube so that the device is wholly encased within the tube. Thus at the stage at which the overwrap is "adapted for use with a device", it is in contact with the device, and so is not being "prepared separately from said device".

This is in contrast to the present invention, which uses a mesh sleeve. The use of a mesh material enables the sleeve to fit snugly over an existing device and allows the sleeve to be prepared separately from the device with which it is to be used. This type of snug fit is not achieved using the non-woven material that is used in D2.

There is a stark difference between an expandable mesh sleeve adapted for use with a device suitable for insertion into a bodily cavity and what is disclosed in D2, namely a non-expandable fabric sack fully enclosing a foam corpus and that forms an integral part of the intra-cavity device.

As D2 in no way discloses or suggests the mesh sleeve of claim 1, claim 1 is novel and inventive over D2.

The remaining claims are novel and inventive over D1 and D2 in light of their dependency on claim 1. The comments regarding individual claims that were made in response to the written opinion still apply. In particular, referring to claim 3, the material sack of D2 fully encloses the device and therefore does not have one open end and one

substantially closed end. Referring to claim 4, it also does not describes a mesh sleeve that is open at both ends.

Referring to claim 5, the material sack of D2 is non-expandable and in fact limits the ability of the foam corpus to expand beyond a certain point. This ability to expand is imparted to the sleeve as a result of the "mesh" nature of the sleeve. In contrast to the comments made by the Examiner during our telephone call, the subject matter of this claim is not couched in terms of a desirable result to be achieved, but recites the technical feature of a "mesh" sleeve – in conjunction with the functional definition of possessing an ability to expand, this recites the novel and inventive features that give rise to advantages possessed by the sleeve over similar devices that are disclosed in the prior art. In addition, the features of an overlap of mesh material and the elasticity of the mesh material, described in claims 6, 7 and 8 that are dependent on claim 5, also define technical features that give rise to the advantageous ability of the mesh sleeve to expand.

I trust that in light of the amendment made to claim 1 and the comments set out above, that the Examiner will now be in a position to issue a positive IPER.

Yours truly,

GOODFELLOW, HUGH ROBIN

Enc: Amended page 20